

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION**

UNITED STATES OF AMERICA

v.

No. 3:15-cr-00496-L

USPLABS, LLC	(1)
JACOBO GEISSLER	(2)
JONATHAN DOYLE	(3)
MATTHEW HEBERT	(4)
S.K. LABORATORIES, INC.	(5)
SITESH PATEL	(6)

**DEFENDANTS USPLABS, LLC, JONATHAN DOYLE, JACOBO GEISSLER,
MATTHEW HEBERT, KENNETH MILES' S.K. LABORATORIES, INC. AND
SITESH PATEL'S MOTION AND BRIEF TO DISMISS COUNT TEN**

Defendants USPlabs, LLC ("USPlabs"), Jonathan Doyle, Jacobo Geissler, Matthew Hebert, Kenneth Miles, S.K. Laboratories, Inc. ("S.K. Labs"), and Sitesh Patel (collectively, "Defendants"), by and through undersigned counsel, respectfully move this Court to dismiss Count Ten of the First Superseding Indictment [Dkt. No. 95, filed Jan. 5, 2016] (the "Indictment") at ¶ 70 a respectfully show the Court as follows.

TABLE OF CONTENTS

I.	SUMMARY OF THE ARGUMENT	1
II.	INTRODUCTION AND BACKGROUND	2
III.	ARGUMENTS AND AUTHORITIES.....	3
A.	Due Process and Rule 7(c)(1) Require the Indictment to Specify the Facts Supporting All Charges, Particularly When the Indictment Alleges Technical Violations of a Regulatory Statute.	4
B.	The Government’s Allegations Regarding Cynanchum Cannot Form The Basis For Count Ten.	7
C.	The Alleged Outbreak of Liver Injuries “Associated” With USPlabs’ Aegeline-Containing Products Cannot Support Count Ten.	8
D.	The Indictment Alleges No Facts Supporting That The Alleged Risk of Illness or Injury Posed By New Formula Exists “Under the Conditions of Use Recommended or Suggested in the Labeling”	11
IV.	CONCLUSION AND PRAYER	13

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Alabama Packing Co. v. United States</i> , 167 F.2d 179 (5th Cir. 1948)	5
<i>Boykin v. United States</i> , 11 F.2d 484 (5th Cir. 1926)	5
<i>Nutraceutical Corp. v. Von Eschenbach</i> , 459 F.3d 1033 (10th Cir. 2006)	9
<i>Russell v. United States</i> , 369 U.S. 749 (1962).....	4
<i>United States v. Bonallo</i> , 858 F.2d 1427 (9th Cir. 1988)	6
<i>United States v. Hess</i> , 124 U.S. 483 (1888).....	4, 5
<i>United States v. Kay</i> , 359 F. 3d 738 (5th Cir. 2004)	4
<i>United States v. Pratt</i> , 728 F.3d 463 (5th Cir. 2013)	5
<i>United States v. Schmitz</i> , 634 F.3d 1247 (11th Cir. 2011)	6
<i>Van Liew v. United States</i> , 321 F.2d 664 (5th Cir. 1963)	5
Statutes	
21 U.S.C.A. § 342(f)(1)(A).....	<i>passim</i>
21 U.S.C. § 331(a)	6
21 U.S.C. § 342(f).....	9
Other Authorities	
21 C.F.R. § 119.1 (2004)	9
S. REP. NO.103-410	8, 9

I. SUMMARY OF THE ARGUMENT

USPlabs is a own-label distributor of dietary supplements; S.K. Laboratories (“SK Labs”) is a contract manufacturer that manufactured USPlabs’ supplements based on formulations and specifications it provided and consulted with USPlabs on. In November 2015, the Government indicted USPlabs, its owners (Defendants Geissler, Doyle and Hebert), its former chief compliance officer (Defendant Miles), its scientific consultant (Defendant Willson), SK Labs, and an SK Labs executive (Defendant Patel) (collectively, Defendants), on a number of counts relating to Defendants’ importation of dietary ingredients and their marketing and sale of dietary supplements containing those ingredients. Count Ten of the Indictment alleges a strict-liability misdemeanor charge against USPlabs, Geissler, Doyle, Hebert, Miles, SK Labs, and Patel for adulteration relating to one supplement that USPlabs marketed for a brief period of time: OxyELITE Pro New Formula (“New Formula”).

The Court should dismiss Count Ten of the Indictment because that Count lacks the specificity required by Rule 7(c)(1) of the Federal Rules of Criminal Procedure, the Fifth Amendment to the U.S. Constitution, and applicable precedent. Although the charging language of the count tracks the statutory language and incorporates by reference conclusory allegations in the Indictment, Count Ten fails to allege the facts constituting the offense with the requisite specificity. Specifically, the Indictment fails to allege any specific facts supporting the allegation that the shipment posed a “significant or unreasonable risk of illness or injury” or what conditions of use were “recommended or suggested in labeling.” *Id.* As such, this count fails to give Defendants notice as to what they must defend at trial. Accordingly, Count Ten must be dismissed.

II. INTRODUCTION AND BACKGROUND

Count Ten of the Indictment charges Defendants with introducing an “adulterated” product into interstate commerce, which by definition is a product that “presented a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling,” in violation of 21 U.S.C. § 342(f)(1)(A)(i). Dkt #95 at ¶ 70. This count arises out of allegations regarding a shipment of OxyElite Pro “New Formula” (also called “Super Thermo” and “Purple Top”) (hereinafter “New Formula”) on or around February 21, 2013. *Id.* New Formula was a new supplement in USPlabs’ line of popular OxyELITE Pro dietary supplements and contained, among others, an ingredient called Aegeline, which is derived from Bael tree, a traditional citrus plant that has been consumed as food since at least 1500 BC.¹

Only two factual allegations in the Indictment can be fairly read to raise any inference that any USPlabs product, let alone New Formula, was adulterated as alleged in Count Ten. First, the Indictment alleges that USPlabs recognized that an ingredient contained in its OxyElite Pro “Advanced Formula” (“Advanced Formula”),² which went on sale in or around August 2013, contained a Chinese herb - *cynanchum auriculatum* (“Cynanchum”) - that the Government contends “could potentially cause ‘liver toxicity.’” *Id.* ¶¶ 31, 32. The Indictment points to no

¹ As related in other motions, OxyELITE Pro originally contained DMAA, a dietary ingredient that is found in geranium, which was extraordinarily successful. USPlabs and other manufacturers of dietary supplements containing DMAA received warning letters from the FDA in April 2012 alleging that DMAA is not a dietary ingredient because it does not occur in geranium. Ex. A. USPlabs responded to the FDA’s warning letter citing to studies showing that DMAA did occur in geranium and was therefore not a new dietary ingredient as the Government alleged. Ex. B. After USPlabs decided nonetheless to remove DMAA from its supplements, another supplement manufacturer, Hi-Tech, brought litigation against the Government; that litigation has revealed that the Government was aware, at the time of the warning letters, that DMAA did occur in geraniums and was not, therefore, a new dietary ingredient as the FDA alleged. Order, *United States v. Quantities of Finished and In-Process Foods, et al.*, 13-CV-3675-WBH (N.D. Ga. Nov. 7, 2013), ECF No. 140.

² Advanced Formula contained both Aegeline and *cynanchum auriculatum* (“Cynanchum”), a plant found throughout Asia that is used in traditional Chinese medicine and long consumed as food. Advanced Formula was first released in August 2013, and was voluntarily taken off the market after only 65 days.

scientific or expert evidence supporting this allegation, and does not allege that Advanced Formula was adulterated.

Second, the Indictment alludes to an outbreak of injuries in fall 2013, “shortly after OxyElite Pro Advanced Formula went on sale,” that was “associated” with USPlabs aegeline-containing products. *Id.* at ¶ 33. Again, the Indictment does not point to a single piece of scientific evidence suggesting any causal link between these purported injuries and the consumption of Advanced Formula. Nor does it allege that these injuries were caused by or were even attributable to the consumption of Advanced Formula. Indeed, Defendants will present (if necessary) expert testimony at trial as to the safety of aegeline and New Formula.

III. ARGUMENTS AND AUTHORITIES

Count Ten should be dismissed because it fails to allege facts showing that any of the Defendants introduced a product that presented a “significant or unreasonable risk of illness or injury . . . under conditions of use recommended or suggested in labeling” and, thus, does not state the charged offense with the specificity required by the Fifth and Sixth Amendments and Fed. R. Crim. P. 7(c)(1).

First, the allegations regarding Cynanchum relate to Advanced Formula, a different product from the one identified in Count Ten. Moreover, Advanced Formula, as the Government acknowledges, was not sold by Defendants until “in or around August 2013,” *see* Indictment ¶ 32, six months after the shipment identified in Count Ten. Those allegations therefore cannot support a charge of adulteration for a product shipped nearly six months earlier, in or around February 2013.

Second, the allegations regarding the purported outbreak of liver injuries merely “associated” with USPlabs do not sufficiently establish a connection between the alleged New Formula shipment and the alleged injuries. The Indictment does not cite to any scientific

evidence or expert testimony supporting a claim that Aegeline posed a risk of injury to any consumer (because there is none). In fact, contemporaneous evidence strongly points to alternative etiologies for the injuries that comprised the purported “outbreak.”³

Third, the Indictment does not allege any facts that would establish that New Formula posed a risk of injury “under the conditions recommended or suggested in the labeling.” *Id.* ¶ 70. Accordingly, the Court should dismiss Count Ten.

A. Due Process and Rule 7(c)(1) Require the Indictment to Specify the Facts Supporting All Charges, Particularly When the Indictment Alleges Technical Violations of a Regulatory Statute.

Federal Rule of Criminal Procedure 7(c)(1) provides, in pertinent part, that the criminal indictment “must be a plain, concise, and definite written statement *of the essential facts constituting the offense charged.*” Fed. R. Crim. P. 7(c)(1) (emphasis added). This is consistent with The Fifth Amendment’s requirement of Due Process, and the Sixth Amendment’s requirement that “In all criminal prosecutions, the accused shall enjoy the right . . . to be informed of the nature and cause of the accusation.” U.S. CONST. amend. V, VI.

Thus, it is well-settled that “all the material facts and circumstances embraced in the definition of the offence *must be* stated, or the indictment will be defective.” *United States v. Hess*, 124 U.S. 483, 486 (1888) (emphasis added). Where an indictment tracks the bare language of the statute, it will be sufficient only if it is “accompanied with such a statement of the facts and circumstances as will inform the accused of the specific offence, coming under the general description, with which he is charged.” *Id.* at 487; *see also Russell v. United States*, 369 U.S. 749, 765 (1962); *United States v. Kay*, 359 F. 3d 738, 756-57 (5th Cir. 2004) (holding that it is not sufficient that the indictment allege the offense in generic terms that parrot the statute where

³ See Ex. C; Ex. D.

the indictment omits factual information that “goes to the very *core of the criminality* under the statute”) (emphasis added). Rather, where “innocuous and morally innocent actions may send men to jail for long periods of time because mistakes in processing or labeling, etc. result in economic adulteration, it is essential that the offense (or offenses) be identified and charged in terms which adequately relate the actions to the statute.” *Van Liew v. United States*, 321 F.2d 664, 674, n.4 (5th Cir. 1963) (finding that the indictment’s charge under 21 U.S.C. §§ 333(a) and 333(b) was “too vague and indefinite, and [did] not sufficiently advise the defendants of the offenses with which they are charged so as to enable them to properly prepare their defense.”). In other words, “facts are to be stated, not conclusions of law alone.” *Hess*, 124 U.S. at 487.

Under this standard, “an indictment must allege[] every element of the crime charged and in such a way as to enable the accused to prepare his defense and to allow the accused to invoke the double jeopardy clause in any subsequent proceeding.” *United States v. Pratt*, 728 F.3d 463, 477 (5th Cir. 2013) (internal quotation marks and citation omitted).

The inclusion of factual allegations supporting the charges in an Indictment is of particular importance where the language of the statute itself lacks specificity. “Where a statute is general, it is not sufficient to merely follow its language in an indictment, but the indictment must allege the specific offense coming under the general description of the statute, in order that the accused may enjoy the right, secured by the Sixth Amendment, ‘to be informed of the nature and cause of the accusation’ against him.” *Boykin v. United States*, 11 F.2d 484, 485 (5th Cir. 1926) (reversing defendant’s conviction and finding “the indictment [was] fatally defective” where “the language used in the indictment [was] as general as [was] the language of the statute”); *Alabama Packing Co. v. United States*, 167 F.2d 179, 181, 182 (5th Cir. 1948) (reversing defendant’s conviction and holding that defendant’s motion to dismiss information for

failure to state an offense should have been granted where “the information contains no allegation of fact charging appellant with the commission of a crime” and the allegation “was a mere conclusion of the pleader”); *see also United States v. Schmitz*, 634 F.3d 1247, 1261-62 (11th Cir. 2011) (reversing conviction on certain counts related to allegations of fraud for failure to state offenses even where indictment tracked the language of the charging statute); *United States v. Bonallo*, 858 F.2d 1427, 1431 (9th Cir. 1988) (“When construing the meaning of an indictment, the description of the alleged conduct is far more critical than the indictment’s prefatory language or its citation of a particular provision of a statute.”).

Section 342(f)(1)(A), the provision in the Food, Drug and Cosmetic Act (“FDCA”) defining “adulteration” as applied to dietary supplements, is precisely the type of general statute that requires additional factual specificity under *Russell* and its progeny. The FDCA prohibits the “introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.” 21 U.S.C. § 331(a). Under the FDCA, as amended by the Dietary Supplement Health and Education Act, Pub.L. No. 103–417 (2000) (“DSHEA”), a product shall be deemed to be “adulterated” if it is a dietary supplement or contains a dietary ingredient that:

presents a significant or unreasonable risk of illness or injury under
 -- (i) conditions of use recommended or suggested in labeling, or
 (ii) if no conditions of use are suggested or recommended in the
 labeling, under ordinary conditions of use.

21 U.S.C.A. § 342(f)(1)(A). The statute provides no further specificity as to when a “risk of illness or injury” is “significant or unreasonable,” or what even constitutes an “illness or injury.” An indictment charging under a statute this general therefore requires more specific allegations to satisfy the Fifth and Sixth Amendments and Rule 7(c)(1).

B. The Government's Allegations Regarding Cynanchum Cannot Form The Basis For Count Ten.

Count Ten is premised on Defendants' shipment into interstate commerce of New Formula made on or around February 21, 2013 that the Government alleges was "adulterated" because it "present[ed] a significant or unreasonable risk of illness or injury under conditions of use recommend or suggested in labeling," all in violation of 21 U.S.C. § 342(f)(1)(A)(i).⁴

The only reference in the Indictment to the alleged use of an ingredient potentially raising any safety concerns relates to Cynanchum. The Indictment alleges that USPlabs "recognized that substance could potentially cause 'liver toxicity,'" *id.* at ¶ 31, and further alleges that Defendants Geissler and Willson did not test Cynanchum's safety. *Id.*⁵

However, these allegations are as irrelevant (and inaccurate) as they are inflammatory, *because Cynanchum was, by the Government's own acknowledgement, not contained in the product on which Count Ten is based.* The charge in Count Ten identifies *New Formula*, not *Advanced Formula*, as the product that is alleged to be adulterated. Indictment ¶¶ 32, 70. Thus, as alleged, Cynanchum was used in a different product (*i.e.*, Advanced Formula) than the product identified in Count Ten (*i.e.*, New Formula), and was not introduced until *six months after* the shipment on which Count Ten was based. Thus, the factual allegations in the Indictment regarding Cynanchum cannot support Count Ten.

⁴ The Count also incorporates by reference the Indictment's preceding allegations. Dkt #95 at ¶ 69.

⁵ These allegations fail to mention that DSHEA does not require any dietary supplement manufacturer to independently test the safety of the ingredients it uses, and permits manufacturers to rely on pre-existing safety studies. As Defendants will prove at trial, this is precisely what USPlabs did in this case, forgoing the inclusion of an ethanol extract of Cynanchum in New Formula based on a review of the studies, and instead including a less concentrated aqueous extract of Cynanchum. Ex. E.

C. The Alleged Outbreak of Liver Injuries “Associated” With USPlabs’ Aegeline-Containing Products Cannot Support Count Ten.

The Indictment also alleges that “[i]n Fall 2013, shortly after OxyElite Pro Advanced Formula went on sale, an outbreak of liver injuries was associated with USPlabs’ products containing aegeline,” and that “[n]umerous consumers experienced jaundice and other liver-related symptoms, and several consumers needed liver transplants in order to save their lives.” Indictment ¶ 33. Yet the allegations related to the 2013 outbreak cannot support the adulteration charge because the Government fails to establish a causal connection between the shipment referenced in Count Ten and the purported outbreak.⁶

Under DSHEA, in order to find a dietary supplement “adulterated,” the FDA must prove that the supplement presents a “significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling....” 21 U.S.C. § 342(f)(1)(A). A finding of adulteration by FDA thus depends on FDA establishing that a significant or unreasonable risk of illness or injury exists under the actual conditions of use recommended by the particular dietary supplement producer. A determination of adulteration requires a dose-specific analysis *through rulemaking*. S. REP. NO.103-410, at 35 (“[S]ection 4 provides new power to the FDA to declare a dietary supplement adulterated *through rulemaking*” (emphasis added)). Congress expressly stated that the government’s ability to satisfy its burden of proof depends upon the particular recommendations suggested in the product’s labeling. S. REP. NO.103-410, at 36 (stating “[t]he government must produce the preponderance of the evidence as to harmful effects from the dietary supplement when used as recommended and suggested in the

⁶ Although the Government conveniently fails to provide any details regarding the alleged outbreak of liver injuries, the alleged “outbreak” is undoubtedly a reference to the cluster of acute hepatitis cases purportedly observed in Hawaii in Fall 2013. Nevertheless, there is no disputable connection here as there is no scientific or medical evidence that aegeline or any version of OxyElite Pro caused the “outbreak” in Hawaii. Rather, an analysis of the medical history of the identified individuals revealed a number of illnesses and alternative etiologies that disprove any causal connection between OxyElite Pro and the identified liver injuries. *See* Ex. C; *see also* Ex. D.

labeling.”) (citation omitted). Indeed, the FDA must publish a finding of adulteration of a dietary supplement and is “required to describe in the notice how such risks are presented under the conditions of use recommended or suggested in labeling.” S. REP. NO.103-410, at 35. Congress intended that a finding of adulteration of a dietary supplement be permitted only if the supplement were proven to present a significant or unreasonable risk of illness or injury in light of the actual product labeling and dosage recommendations. S. REP. NO.103-410, at 36 (“A safety finding cannot be entered against a supplement based upon a dosage not recommended to consumers in the labeling.”).⁷

FDA’s treatment of ephedrine-alkaloid dietary supplements (EDS) provides some guidance as to what establishes that a dietary supplement presents an “unreasonable risk” of illness or injury. In 2004, FDA promulgated a final rule banning EDS after declaring them to be “adulterated” because they presented an unreasonable risk of illness or injury. 21 C.F.R. § 119.1 (2004); *Nutraceutical Corp. v. Von Eschenbach*, 459 F.3d 1033, 1036 (10th Cir. 2006). With this, Final Rule provided the FDA’s understanding of the meaning “unreasonable risk” as follows:

The Government's burden of proof for “unreasonable risk” is met when a product’s risks outweigh its benefits in light of the claims and directions for use in the product's labeling or, if the labeling is silent, under ordinary conditions of use. “*Unreasonable risk*,” thus, represents a relative weighing of the product’s known and

⁷ DSHEA also contemplates a regulatory process short of a criminal indictment by which the FDA can notify parties of its intent to declare a dietary supplement to be adulterated. See 21 U.S.C. § 342(f); see also S. Rep. No.103-410, at 3 (“This section reaffirms the current standard for adulteration of dietary supplements (under section 402(a)(1) of the Federal Food Drug and Cosmetics Act (FFD&CA)), but requires the finding to be based on conditions of use recommended or suggested in the labeling. In addition, a dietary supplement is adulterated if FDA finds, after rulemaking, that the ingredient presents a substantial and unreasonable risk of illness or injury under conditions or use recommended or suggested in labeling.”); S. REP. NO. 103-410 at 22 (“Under the amendment, a dietary supplement would be deemed adulterated in any one of three situations: [1] If the Secretary finds that it contains a poisonous or deleterious substance injurious to health. . . [2] If the Secretary finds, after informal rulemaking, that the supplement “presents a substantial and unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling” . . . [3] If the Secretary, as a non-delegable exercise of authority, declares the supplement “to pose an imminent and substantial hazard to public health or safety.”).

reasonably likely risks against its known and reasonably likely benefits. In the absence of a sufficient benefit, the presence of even a relatively small risk of an important adverse health effect to a user may be unreasonable. Because it is not reasonable to conclude that a product is too risky in the absence of any significant evidence, some weight of evidence of risk is required to meet this standard.

Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk, 69 Fed. Reg. 6788-01 (Feb. 11, 2004) (codified at 21 C.F.R. pt. 119) (emphases added).

In contrast to the FDA's proceedings on EDS, here, the Government never undertook an administrative proceeding, as DSHEA requires, to declare Aegeline or OEP adulterated. If FDA believed that any USPlabs product fell within the contemplated definition of an "adulterated" dietary supplement, it could have pursued regulatory action by proposing a rule declaring that the product was adulterated and permitted Defendants to submit evidence-based comments as to why the product should not be deemed adulterated. Rather than initiating this more deliberative, fact-driven regulatory action in this case, it has conveniently avoided any regulatory fact-finding by skipping this process and criminally charging Defendants with adulteration as a strict-liability misdemeanor.

Though the Indictment states that New Formula contained aegeline and alleges that the FDA conducted an inspection in October 2013 to "identify whether USP Labs' products were the source of the liver injury outbreak," Indictment ¶ 34, it is devoid of any factual allegations, testing results, or other findings - whether relating to that inspection or otherwise - that would support a conclusion that New Formula presented "significant or unreasonable risk of illness or

injury under the conditions of use recommended or suggested in the labeling.”⁸ The best the Government can do, nearly two years after its “emergency” inspection and any testing or research that it performed on the product in the two years between that inspection and the filing of the Indictment, is to allege (other than in its recitation of the language of § 342(f)(1)(A)(i)) that New Formula – without reference to any specific dietary ingredient - presented a “a significant and unreasonable risk” of harm to consumers. Indictment ¶ 33. The Indictment does not cite to any scientific testing or research or expert evidence supporting the allegation that “USPlabs’ products containing aegeline” were a likely, probably or even possible cause of the purported liver injury outbreak, nor does it allege that the alleged victims of the outbreak even consumed New Formula from the February 2013 shipment identified in Count 10. Mere “association” (in other words, correlation, not causation) between Defendants’ products and an outbreak that occurred six months after the shipment of New Formula alleged to be adulterated simply cannot form the basis of charging Defendants with selling a product that presented a “significant and unreasonable risk” to consumers.⁹

D. The Indictment Alleges No Facts Supporting That The Alleged Risk of Illness or Injury Posed By New Formula Exists “Under the Conditions of Use Recommended or Suggested in the Labeling”

For a dietary supplement to be deemed adulterated under the FDCA, the government must prove that the product “presents a significant or unreasonable risk of illness or injury *under conditions of use recommended or suggested in labeling.*” 21 U.S.C. § 342(f)(1)(A) (emphasis

⁸ USPlabs’ counsel has requested that the Government provide details as basic as what particular dietary ingredient the Government contends caused New Formula to be adulterated, as well as other information to allow Defendants to prepare their defense to this claim. To date, the Government has declined to respond with any additional specificity.

⁹ See, e.g., Ex. D.

added). Thus, a key element to the crime of adulteration relates to the recommended uses and instructions that appear on the product's labeling.

The Indictment fails to allege *any* facts regarding the warnings on New Formula's label, which contained very specific instructions and warnings about how to use the product. USPlabs marketed New Formula between November 2012 through November 2013. Throughout this time, under "Directions for Use," the label instructed consumers: "Consult with your physician before using this product." *See* Ex. F. In addition, in large, bold, and capitalized font, the label provided the following instructions:

UNDER NO CIRCUMSTANCES SHOULD INITIAL SERVING SIZE BE EXCEEDED OF THE WARNINGS ON THIS BOTTLE IGNORED. DO NOT USE PRODUCT FOR LONGER THAN 8 WEEKS FOLLOWED BY A SUBSEQUENT 4 WEEK BREAK. DO NOT EXCEED 3 CAPSULES IN ANY 24 HOUR PERIOD.

Id. The label also listed the following warning:

WARNING: DO NOT USE IN COMBINATION WITH CAFFEINE OR ANY STIMULANTS FROM OTHER SOURCES WHATSOEVER, INCLUDING BUT NOT LIMITED TO, COFFEE, TEA, SODA, AND OTHER DIETARY SUPPLEMENTS OR MEDICATIONS. DO NOT USE UNDER EXTREME CONDITIONS OF HEAT, SLEEP DEPRIVATION OR DEHYDRATION. DO NOT COMBINE WITH ALCOHOL. This product is only intended to be consumed by healthy adults 18 years of age or older. **Consult with your Physician before using this product**, especially if you are using any prescription or over the counter blood pressure, cardiac arrhythmia, stroke, heart, liver, kidney or thyroid disease, seizure disorder, MAOI (Monoamine Oxidase Inhibitor) or any other medication.

Id. (emphasis in original).

The Government fails to allege how, when used in accordance with these warnings and instructions, the alleged shipment referenced in Count Ten nevertheless caused a significant or unreasonable risk of illness or injury. The Indictment is absent any allegations as to the types of

consumers who were allegedly injured by New Formula (*e.g.*, whether they were healthy adults, whether they consulted with their physicians, whether they were taking any other medication), or whether they were using New Formula consistent with its directions for use (*e.g.*, whether they were taking New Formula with any of the products enumerated in the warning, whether they were taking the product beyond the recommended time period). The Indictment leaves Defendants without a clue as to whether the alleged victims of the liver injury outbreak “associated” with USPlabs products used New Formula at all, let alone whether they used it under the conditions of use recommended or suggested in its labeling. Count Ten thus fails to meet the requisite specificity necessitated by constitutional requirements and Fed. R. Crim. P. 7(c)(1) and, therefore, should be dismissed.

IV. CONCLUSION AND PRAYER

For the reasons set forth above, Count Ten fails to state the offense with requisite specificity. Accordingly, Defendants respectfully request that the Court dismiss Count Ten of the Indictment.

Respectfully submitted:

/s/ CHRISTOPHER NIEWOEHNER

Christopher Niewoehner (admitted *pro hac vice*)

Illinois Bar No. 6243575

Reid Weingarten (admitted *pro hac vice*)

Patrick F. Linehan (admitted *pro hac vice*)

David Fragale (admitted *pro hac vice*)

STEPTOE & JOHNSON LLP

1330 Connecticut Ave. NW

Washington, DC 20036

Phone: (202) 429-3000

Fax: (202) 429-3902

rweingarten@steptoe.com

Michael John Uhl

Texas Bar No. 20371050

FITZPATRICK HAGOOD SMITH & UHL

2515 McKinney Ave.

Dallas, TX 75201

Phone: (214) 237-0900

Fax: (214) 237-0901

muhl@fhsulaw.com

**ATTORNEYS FOR DEFENDANT
USPLABS, LLC**

/s/MICHAEL P. GIBSON

Michael P. Gibson

Texas Bar No. 07871500

BURLESON PATE & GIBSON LLP

900 Jackson Street

Suite 330

Dallas, TX 75202

Phone: (214) 871-4900

Fax: (214) 871-7543

Email: mgibson@bp-g.com

**ATTORNEY FOR DEFENDANT
JACOBO GEISLER**

/s/ RICHARD B. ROPER

Richard B. Roper

Texas Bar No. 01723370

THOMPSON & KNIGHT LLP

1722 Routh Street

Suite 1500

Dallas, TX 75201

Phone: (214) 969-1700

Fax: (214) 969-1751

**ATTORNEY FOR DEFENDANT
JONATHAN DOYLE**

/s/ S. CASS WEILAND

S. Cass Weiland

Texas Bar No. 21081300

SQUIRE PATTON BOGGS (US) LLP

2000 McKinney Ave.

Suite 1700

Dallas, TX 75201

Phone: (214) 758-1504

Fax: (214) 758-1550

Email: cass.weiland@squirepb.com

**ATTORNEY FOR DEFENDANT
MATTHEW HEBERT**

/s/ JOSEPH L SHEARIN

Joseph L Shearin

Law Offices of Joe Shearin

Texas Bar No.

2515 McKinney Ave

Suite 1400

Dallas, TX 75201

214/267-1000

Fax: 214/237-0901

Email: joeshearin@shearinlaw.net

**ATTORNEY FOR DEFENDANT
KENNETH MILES**

/S/ JOSEPH M. MCMULLEN

Joseph M. McMullen

Cal. Bar No.

Law Offices of Joseph M. McMullen

225 Broadway Suite 1460

San Diego, CA. 92101

(619)501-2000

(619) 615-2264

joe@jmm-legal.com

ATTORNEY FOR DEFENDANT

S.K. LABORATORY INC.

(admitted *pro hac vice*)

/S/ PATRICK Q. HALL

Patrick Q. Hall

Cal. Bar No.

Law Offices of Patrick Q. Hall

California Bar No. 97019

401 B Street, Suite 2220

San Diego, CA. 92101

(619) 268-4040

pat@pqhlaw.com

ATTORNEY FOR DEFENDANT

SITESH PATEL

(admitted *pro hac vice*)

CERTIFICATE OF SERVICE

On May 1, 2017, I electronically submitted the foregoing document with the clerk of the court of the U.S. District Court, Northern District of Texas, using the electronic case filing system of the court. I hereby certify that I have served the U.S. Probation Officer, all counsel of record electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2), and the probation officer assigned to the case.

/s/ Richard B. Roper
Richard B. Roper